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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,751	12/14/2005	Olivier Lambert	ON/4-33220A	3065
1095 NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080				
EXAMINER				
HA, JULIE				
ART UNIT		PAPER NUMBER		
1654				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/560,751

Applicant(s)

LAMBERT ET AL.

Examiner

JULIE HA

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 10-14 is/are pending in the application.
4a) Of the above claim(s) 10 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-6 and 11-14 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/5508)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Amendment after Non-final rejection filed on June 5, 2008 is acknowledged. Claims 1-6 and 10-14 are pending in this application. Claim 10 remains withdrawn from further consideration, as being drawn to nonelected species. Claims 1-6 and 11-14 are examined on the merits in this office action.

Withdrawn Objection and Rejection

1. Objection to claim 1 has been hereby withdrawn in view of Applicant's amendment to the claim.
2. Rejection of claim 1 under 35 U.S.C. 112, 2nd paragraph, is hereby withdrawn in view of Applicant's amendment to the claim.

Maintained Rejection

35 U.S.C. 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
6. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al (US Patent # 5059587).
7. The instant claim is drawn to a liquid formulation for parenteral administration comprising a somatostatin analogue comprising the amino acid sequence of formula I and tartaric acid.
8. Yamamoto et al teach a nasal administration powder composition containing a physiologically active peptide as an active ingredient can be efficiently absorbed through nasal mucosa by the addition of a water-soluble organic acid as an absorption promoter (see abstract). The reference further teaches that injections often cause pains and are not preferred (see column 1, lines 18-20). The reference teaches that the physiologically active peptides which are active ingredients in the composition include peptide hormones, proteins and enzymes which have physiological activity such as

calcitonin gene related peptides (CGRP), calcitonin, parathyroid hormone (PTH), insulin, somatostatin, growth hormone, secretin, gastrin, vaspressin, oxytocin...(see column 2, lines 25-40). The reference lists about 20 physiologically active peptides. The reference further teaches that the water-soluble organic acids are succinic acid, tartaric acid, citric acid, fumaric acid...(see column 3, lines 23-28 and claim 1). Furthermore, the reference teaches that the nasal administration powdered composition is superior to the conventional liquid preparations for nasal administration of peptide hormone in terms of stability of active ingredients...(see column 4, lines 42-54). Furthermore, the reference teaches that nasal administration powdered composition is much superior to the conventional nasal administration powdered preparations in absorbability through nasal mucosa (see column 4, lines 55-58 and column 1, lines 50-54, "Summary of the Invention"). This reads on claim 1, since nasal administration is a species of parenteral administration. The difference between the reference and the instant claim is that the reference does not teach the somatostatin analog comprising the amino acid sequence of formula I.

9. Therefore, it would have been obvious to one of ordinary skilled in the art to substitute the somatostatin taught in Yamamoto et al for the somatostatin analog, since these analogs may be more potent. There is a reasonable expectation of success since Yamamoto et al teach that tartaric acid and active peptide complex is more stable and has higher absorbability through nasal administration. Further, nasal administration would not cause the pains of injections as disclosed by Yamamoto et al.

Response to Applicant's Arguments

10. Applicant argues that "Yamamoto relates to powdered nasal administration compositions." Furthermore, Applicant argues that "Yamamoto teaches away from injections because they often cause pain. By contrast, the present invention relates to liquid parenteral formulations suitable for injection." Further, Applicant argues that "Yamamoto discloses tartaric acid among a list of organic water soluble acids, whereas the present invention specifically teaches compositions comprising tartaric acid....also, the tartaric acid is the key advantage of the subcutaneous formulation."

11. Applicant's arguments have been fully considered but have not been found persuasive because Yamamoto teaches parenteral formulation of a somatostatin analogue comprising the same physiologically active peptide as the instant claims. Furthermore, there are only several parenteral formulations that are readily available to one of ordinary skill in the art, injection being one of them. Although, Yamamoto indicates that it is preferred that the parenteral route is not through injection due to pain, such a teaching does not imply that injections should be avoided. In the same sentence, the reference states other routes of administration have not been put to practical use due low absorption rates as compared to injections. Furthermore, Yamamoto specifically discloses administration of the peptide via injection (see example 18). Reading the reference as a whole would not lead one to conclude that injection should be avoided and is discouraged. It would have been obvious to one of ordinary skill in the art to try to formulate into injection, since it is one of the main route to the blood stream. Yamamoto claims a composition having calcitonin activity as an active

ingredient and water-soluble organic acid as an absorption promoter and tartaric acid is one of the water-soluble organic acid that is claimed. Although Yamamoto teaches a powder form suitable for nasal administration, it would have been obvious to one of ordinary skill in the art to formulate the composition as a liquid form for injection. Applicant is reminded that the intended use has not been given any patentable weight, since they do not further limit the compound. Additionally, Yamamoto teaches a composition comprising the same components, therefore the reference is *prima facie* obvious over the instant claim.

12. Claims 2-5 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al (US Patent # 5059587) in view of Albert et al (WO 02/10192).

13. The instant claims are drawn to a liquid formulation for parenteral administration comprising a somatostatin analog comprising the amino acid sequence of formula I (in aspartate di-salt form) and II and tartaric acid, and a pharmaceutical composition wherein the somatostatin analog is cyclo[$\{4\text{-NH}_2\text{-C}_2\text{H}_4\text{-NH-CO-O}\}$ Pro]Phg-DTrp-Lys-Tyr(4Bzl)-Phe].

14. Yamamoto et al teach a nasal administration powder composition containing a physiologically active peptide as an active ingredient can be efficiently absorbed through nasal mucosa by the addition of a water-soluble organic acid as an absorption promoter (see abstract). The reference further teaches that injections often cause pains and are not preferred (see column 1, lines 18-20). The reference teaches that the physiologically active peptides which are active ingredients in the composition include

peptide hormones, proteins and enzymes which have physiological activity such as calcitonin gene related peptides (CGRP), calcitonin, parathyroid hormone (PTH), insulin, somatostatin, growth hormone, secretin, gastrin, vaspressin, oxytocin...(see column 2, lines 25-40). The reference lists about 20 physiologically active peptides. The reference further teaches that the water-soluble organic acids are succinic acid, tartaric acid, citric acid, fumaric acid...(see column 3, lines 23-28 and claim 1). This reads on claim 1. Furthermore, the reference teaches that the nasal administration powdered composition is superior to the conventional liquid preparations for nasal administration of peptide hormone in terms of stability of active ingredients...(see column 4, lines 42-54). Furthermore, the reference teaches that nasal administration powdered composition is much superior to the conventional nasal administration powdered preparations in absorbability through nasal mucosa (see column 4, lines 55-58 and column 1, lines 50-54, "Summary of the Invention"). Additionally, the reference teaches that the water-soluble organic acid is at least in such an amount that the aqueous solution of the powdered composition is acidic...water soluble organic acid is added until the pH is not more than about 4 when the composition (10 mg) is dissolved in water (1 ml) (see column 4, lines 1-7). Furthermore, the reference teaches that to the resulting lyophilized powder is added water-soluble organic acid or are added water-soluble organic acid and diluent, and these are mixed to obtain a homogeneous composition (see column 4, lines 23-27). The difference between the reference and the instant claims is that the reference does not teach cyclo[$\{4\text{-NH}_2\text{-C}_2\text{H}_4\text{-NH-CO-O}\}$ Pro]Phg-DTrp-Lys-Tyr(4Benzyl)-Phe].

15. However, Albert et al discloses cyclo[{4-NH₂-C₂H₄-NH-CO-O)Pro]Phg-DTrp-Lys-Tyr(4Benzyl)-Phe], optionally in protected form, or a pharmaceutically acceptable salt or complex thereof (see abstract). Additionally, the structural formula of instant claim 2 is shown in paragraph 2 and described in paragraph 3 as cyclo[{4-NH₂-C₂H₄-NH-CO-O)Pro]Phg-DTrp-Lys-Tyr(4Bzl)-Phe] and is referred to as compound A (see paragraphs [0002] and [0003], structure of formula on p. 1 and claim 1). The reference further teaches that compound A or a pharmaceutically acceptable salt or complex thereof may be administered by any conventional route, for example parenterally (see p. 15, paragraph 4). Furthermore, the reference teaches that compound A may exist in free or salt form. Preferred salt are lactate, aspartate, benzoate, succinate and pamoate including mono- and di-salts, more preferably the aspartate di-salt (see p. 3, paragraph 4).

16. Therefore, it would have been obvious for one of ordinary skill in the art to combine the teachings of Yamamoto et al and Albert et al to produce a pharmaceutical composition for parenteral administration comprising a somatostatin analog and tartaric acid, because both prior arts teach a pharmaceutical composition for parenteral administration of physiologically active peptide (somatostatin) and analogs may be more potent. There is a reasonable expectation of success since powdered nasal administration composition containing peptide hormone as an active ingredient and tartaric acid (organic acid) is superior in safety and stability and from which the active ingredient can be fully absorbed through the nasal cavity (see Yamamoto, column 1, lines 50-54). Furthermore, Yamamoto et al list about 20 active peptide, thus one of

ordinary skilled in the art would at once envisage the composition of somatostatin and tartaric acid for nasal administration composition. Furthermore, Yamamoto et al teach that the conventional liquid preparations for nasal administration of peptide hormone, surface active agents are used as absorption promoter, which are highly irritative against nasal mucosa and preservatives are used for preventing contamination with microorganisms, which cause harmful effects...However, nasal administration powdered composition using tartaric acid as absorption promoter suffer from no such problems (see column 4, lines 45-54). Furthermore, there is a reasonable expectation of success to formulate the composition into any pharmaceutically acceptable formulation, including injection, since both prior arts teach a pharmaceutical composition for parenteral administration of physiologically active peptide.

17. Claims 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al (US Patent # 5059587) in view of Albert et al (WO 02/10192) as applied to claims 1-5 and 11-12 above, and further in view of Stalla et al (European Journal of Endocrinology, 1994, 130: 125-131).

18. The instant claims are a method of treating Cushing's Disease comprising administering a pharmaceutical composition, wherein the somatostatin analog is cyclo[4-NH₂-C₂H₄-NH-CO-O)Pro}-Phg-DTrp-Lys-Tyr(4Bzl)-Phe].

19. The teachings of Yamamoto et al and Albert et al (WO 02/10192) are described, supra. The difference between the reference and the instant claims is that the reference does not teach a method of treating Cushing's Disease.

20. However, Stalla et al teach that somatostatin analog octreotide (SMS 201-995) had different effects in vivo and in vitro in Cushing's disease (see Title). The reference teaches that octreotide could inhibit the ACTH release from human corticotrophic adenoma cells in vitro but had no suppressive effect on ACTH levels of patients with Cushing's disease in vivo (see abstract). The reference teaches that octreotide suppressed ACTH serum levels in patients with adrenal insufficiency (Addison's disease) and in patients with Nelson's syndrome. This indicates that human corticotrophic adenoma cells contain somatostatin receptors (see p. 125). The reference explains that since octreotide suppressed ACTH serum levels in both Addison's and Nelson's disease, the in vivo and in vitro discrepancy with Cushing's disease may be due to a somatostatin receptor down-regulation by cortisol at the hypercortisolemic state in vivo (see p. 125, 2nd paragraph).

21. Therefore, it would have been obvious to one of ordinary skill in the art to combine the teachings of Albert et al, Yamamoto et al and Stalla et al to treat Cushing's disease. Albert et al teach somatostatin analogs, Yamamoto et al teach nasal administration powder composition containing a physiologically active peptide, such as somatostatin, and Stalla et al teach somatostatin analog in treating Cushing's Disease in vivo and in vitro, therefore, there is a reasonable expectation of success, since all teach somatostatin or its analog. Furthermore, there is a reasonable expectation of success to formulate the composition into any pharmaceutically acceptable formulation, including injection, since both prior arts teach a pharmaceutical composition for parenteral administration of physiologically active peptide. And since Stalla et al teach

treatment of Cushing's Disease, there is motivation of success, since all prior arts teach somatostatin or its analogs, and Yamamoto et al teach a noninvasive (nasal administration) means of administration. Additionally, since Albert et al teach the compounds are useful for the treatment of malignant cell proliferative diseases, e.g. cancer tumors, particularly tumors bearing the somatostatin receptor types targeted by the compounds (see p. 20, 3rd paragraph) and that corticotropic adenoma cells contain somatostatin receptors (see Stalla), it would have been obvious to use somatostatin analogs for treatment for Cushing's disease.

22. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albert et al (WO 02/10192) in view of Kamber B (US Patent # 4603120) and further in view of Bodmer et al (US Patent # 5639480).

23. The instant claims are drawn to a liquid formulation for parenteral administration comprising a somatostatin analog wherein the composition is buffered by an acetate/acetic acid, lactate/lactic acid or glycine/HCl buffer to about pH 4 to about pH 4.5.

24. Albert et al discloses cyclo[[4-NH₂-C₂H₄-NH-CO-O)Pro]Phg-DTrp-Lys-Tyr(4Benzyl)-Phe], optionally in protected form, or a pharmaceutically acceptable salt or complex thereof (see abstract). Additionally, the structural formula of instant claim 2 is shown in paragraph 2 and described in paragraph 3 as cyclo[[4-NH₂-C₂H₄-NH-CO-O)Pro]Phg-DTrp-Lys-Tyr(4Bzl)-Phe] and is referred to as compound A (see paragraphs [0002] and [0003], structure of formula on p. 1 and claim 1). This reads on claim 5. The

reference further teaches that compound A or a pharmaceutically acceptable salt or complex thereof may be administered by any conventional route, for example parenterally (see p. 15, paragraph 4). This further reads on claim 5. Furthermore, the reference teaches that compound A may exist in free or salt form. Preferred salt are lactate, aspartate, benzoate, succinate and pamoate including mono- and di-salts, more preferably the aspartate di-salt (see p. 3, paragraph 4). The difference between the reference and the instant claims is that the reference does not teach the pH of about 4 to about 4.5 and the composition is buffered by an acetate/acetic acid, lactate/lactic acid or glycine/HCl buffer.

25. However, Kamber B teach cyclopeptides of the somatostatin type and processes for their manufacture, and to pharmaceutical preparations containing these compounds and the use of these compounds or preparations for therapeutic purposes (see column 1, lines 7-11). Furthermore, the reference teaches the preparations may be used especially for parenterally administration (see column 15, lines 51-54). Furthermore, the reference teaches that preparations for parenteral administration in single-dose form...contain a buffer, for example a phosphate buffer, that is to maintain the pH between approximately 3.5 and 7, and also sodium chloride, mannitol or sorbitol for adjusting the isotonicity (see column 16, lines 1-9). The difference between the prior arts and the instant claims is that the reference does not teach the acetate buffer system.

26. However, the Bodmer et al teach microparticles comprising a somatostatin or an analog or derivative thereof (ocetretide) in a buffer system that may be prepared from

acidic buffers such as phosphate buffer, acetate buffer and the like and the buffer may be from pH 2 to 8 with a pH 4 preferred (see abstract and column 9, lines 3-8). Further, the reference teaches that the microparticles can be administered in conventional manner, e.g. subcutaneous or intramuscular injection (see column 12, lines 6-7).

27. Therefore, it would have been obvious to one of ordinary skill in the art to combine the teachings of Albert et al, Kamber and Bodmer et al to administer the somatostatin in a buffer system containing acetate because for parenteral use, buffers such as phosphate and acetate can be used. There is a reasonable expectation of success, since all prior arts teach parenteral administration of somatostatin or analog thereof and Kamber teaches that parenteral administration in single-dose form contain a buffer, for example, a phosphate buffer, that is to maintain the pH between approximately 3.5 to 7 and Bodmer et al teach that emulsion may be buffered with a buffer which is non-detrimental to the peptide and the polymer matrix material (see column 9, lines 5-7). Thus, it would have been obvious to provide the composition in a buffer system (acetate buffer) to maintain the activity and inhibit the degradation of the somatostatin.

Response to Applicant's Arguments

28. Applicant argues that "Yamamoto relates to powdered nasal administration compositions." Furthermore, Applicant argues that "Yamamoto teaches away from injections because they often cause pain. By contrast, the present invention relates to liquid parenteral formulations suitable for injection." Further, Applicant argues that

"Yamamoto discloses tartaric acid among a list of organic water soluble acids, whereas the present invention specifically teaches compositions comprising tartaric acid....also, the tartaric acid is the key advantage of the subcutaneous formulation."

29. Applicant's arguments have been fully considered but have not been found persuasive as described above in regards to Yamamoto reference. Yamamoto teaches parenteral formulation of a somatostatin analogue comprising the same physiologically active peptide as the instant claims. Furthermore, there are only several parenteral formulations that are readily available to one of ordinary skill in the art, injection being one of them. Although, Yamamoto indicates that it is preferred that the parenteral route is not through injection due to pain, such a teaching does not imply that injections should be avoided. In the same sentence, the reference states other routes of administration have not been put to practical use due low absorption rates as compared to injections. Furthermore, Yamamoto specifically discloses administration of the peptide via injection (see example 18). Reading the reference as a whole would not lead one to conclude that injection should be avoided and is discouraged. It would have been obvious to one of ordinary skill in the art to try to formulate into injection, since it is one of the main route to the blood stream. Yamamoto claims a composition having calcitonin activity as an active ingredient and water-soluble organic acid as an absorption promoter and tartaric acid is one of the water-soluble organic acid that is claimed. Although Yamamoto teaches a powder form suitable for nasal administration, it would have been obvious to one of ordinary skilled in the art to formulate the composition as a liquid form for injection. Furthermore, the intended use has not been

given any patentable weight, since they do not further limit the compound. Additionally, Yamamoto teaches a composition comprising the same components, therefore the references combined are prima facie obvious over the instant claim.

Conclusion

30. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). No claims are allowed.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. H./
Examiner, Art Unit 1654

/Anish Gupta/
Primary Examiner, Art Unit 1654